FOOD MARKETING INSTITUTE

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September 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Program Priorities in the Center for Food Safety and Applied Nutrition (Docket No. 98N-0359)

Dear Sir or Madam:

The Food Marketing Institute is pleased to respond to the Food and Drug Administration's (FDA's) request for comments concerning the establishment of program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) in the year 2000. 64 Fed. Reg. 47845 (Sept. 1, 1999). We have made several recommendations below in each of the categories identified by the Agency in the Federal Register notice, and we urge you to consider each of these fully. We particularly call your attention to the following: our request that FDA clear the use of irradiation for ready-to-eat foods; our recommendation that the Agency develop a clear and consistent food safety labeling policy; and our suggestion that a Retail Advisory Committee be formed to guide FDA with respect to the operational aspects relevant to ensuring food safety at retail. The establishment of a Retail Advisory Committee is essential to ensuring the development of sound, practical food safety programs for the retail environment.

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

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1. Issues Directly Related to Consumer Safety

a. Clearance of Irradiation for Ready-to-Eat Foods

Irradiation is an important tool in the effort to improve the safety of the food supply. We were pleased that the Agency revisited the issue of labeling irradiated foods earlier this year. In response to FDA's advance notice of proposed rulemaking (64 Fed. Reg. 7834 (Feb. 17, 1999)), we expressed our support for the use of informative labeling to advise consumers that certain foods have been irradiated. Moreover, we recommended that FDA clarify the regulation to expressly permit the use of labeling that connects the irradiation process with its benefits, *e.g.*, "Irradiated to kill harmful bacteria."

With respect to ready-to-eat foods, FMI is pleased to be a member of the Food Irradiation Coalition, which submitted a petition to FDA in August. The petition asks the Agency to amend the food additive regulations to permit the use of irradiation in the treatment of certain refrigerated, frozen, or dried food products derived from meat, poultry, fruits or vegetables to help control microbial pathogens and infectious protozoa. We urge the Agency to review and act on the petition quickly so that irradiation will be available as a food safety tool for ready-to-eat food products.

An equally important element to ensuring the ultimate use of irradiation will be educating consumers about the benefits of irradiation and de-bunking the myths that have developed around food irradiation. In this regard, we have welcomed the opportunity to assist the Agency in the development of an educational brochure. However, we recognize that more extensive educational efforts are likely to be necessary before the public will accept irradiation as a food safety tool without reservation.

b. Assessment of Consumer Warnings and Labeling

Under the current regulations, FDA requires or has proposed consumer warning labels on a variety of different food products, such as unpasteurized juice and shell eggs. In addition, the U.S. Department of Agriculture (USDA) requires warning labels on certain meat and poultry products under the Federal Meat Inspection Act and the Poultry Products Inspection Act. Each of the warning labels is visually and substantively different. Although some element of differentiation is necessary, there is little doubt that the multitude of warnings is confusing to consumers overall. The proliferation of warning labels on food and other consumer products has led consumers to discount or disregard warnings on foods. Moreover, labeling, in and of itself, does little to protect the public health.

Therefore, the Agency should develop a clear and coordinated policy for when and how warning labels are used on foods. Furthermore, FDA should, in conjunction with the other food safety agencies, develop a more uniform design for warning labels for those instances in which the Agency determines that such a label is appropriate. For

example, the Partnership for Food Safety, of which FDA is a member, has developed food safety messages and icons that might form the basis for a uniform food safety labeling system.

c. Redefinition of Food Code's Definition of "Potentially Hazardous Food"

The Food Code includes a lengthy definition of the term "potentially hazardous food." U.S. Public Health Service, *Food Code* § 1-201.10(B)(61) (1999). The Food Code relies in part on the acidity level and water activity of foods to identify foods that are potentially hazardous. However, the results of recent research and outbreaks indicate that this view does not account for the synergistic effects of additives and preservatives, which may not affect acidity or water activity. The data also suggest that some foods that are currently exempted from the potentially hazardous food definition on the basis of acidity or water activity (*e.g.*, citrus juices, cooked ready-to-eat products, and certain fruits and vegetables) might, in fact, be hazardous. To ensure that foods are handled properly, it is important to ensure that the potentially hazardous food definition is modified to reflect the most current scientific data.

2. Specific Top Priorities

a. Development of Retail Advisory Committee

FDA currently receives advice and guidance from several joint advisory committees, some of which serve both FDA and USDA. Given the increased focus on retail food safety issues, we recommend that FDA develop a "Retail Advisory Committee" to provide guidance to the agencies on the operational and practical issues relevant to food safety at the retail level. The Committee might be comprised of members from the supermarket, restaurant, and food technology industries, along with other scientific experts.

Moreover, existing advisory committees, such as the National Advisory Committee on Microbiological Contamination of Foods (NACMCF), would benefit from the insight of the retail perspective. For example, the NACMCF recently considered the merits of gloved and bare-hand contact of food in the retail setting. However, none of the committee members represents the retail sector. In light of the growing attention that food safety in the retail setting is receiving at the federal level, an increased presence of retail members on the federal advisory committees will help to formulate better food safety recommendations and bring new knowledge and expertise not currently available on the federal committees.

b. Joint Government-Industry Partnership for Education of Food Handlers

The importance of well-educated food handlers cannot be underestimated in the effort to strengthen the safety of the food supply. In this regard, FMI members participate in a variety of programs for training and certification of food handlers. While we are pleased to be part of a collaborative industry effort, we believe such programs would be strengthened by the participation and endorsement of the Food and Drug Administration. When a particular activity, behavior, or food handler issue arises that needs special attention, such as proper handwashing and gloving techniques, a joint government-industry program would have the benefit of standardized content and methods of training, which we believe would ensure the highest caliber training program for food handlers.

c. Integrated Food Safety System

FDA is cooperating with the Association of Food & Drug Officials (AFDO) in developing an integrated food safety system that incorporates and defines the roles of the federal, state, and local agencies in the pursuit of food safety. As we understand it, under the integrated system, FDA will develop and clarify uniform policies, and the state and local governments will take the lead in enforcing those policies. The purpose of the system is to identify and eliminate redundancies.

FMI agrees that the approach set forth under the integrated food safety system is a sound one. However, we also believe that industry should assist in the development of the program. Industry participation would assure that the resulting programs are applicable to "real-world" food retail settings, and that they are clearly understood by the industry. Participation by industry members will also establish industry "buy-in" to greater assure the success of the program. A better overall program can be achieved by government/industry collaboration.

3. Research Priorities

a. *Listeria monocytogenes* Research

Research should be conducted to determine effective control and detection methods for *Listeria monocytogenes* (Lm) at the distribution and retail stages of the food production continuum. Although a fair amount of data is available on methods to control Lm at the processing stage, more information is needed on practical interventions with respect to Lm at retail. The risk assessment could also establish acceptable levels of Lm based on product grouping in keeping with similar actions initiated by Canada and Europe.

b. Produce Risk Assessment

FDA should collaborate with USDA and academia to conduct a thorough risk assessment of produce items in order to identify control gaps and determine practical interventions. A comprehensive farm-to-table approach is necessary to ensure the safety of produce since many fruits and vegetables are ready-to-eat foods that may not be cooked prior to consumption. Accordingly, reasonable interventions should be developed and the appropriate points of implementation on the production chain should be identified to ensure the safety of the produce supply. FDA applied this approach in the development of Good Agricultural Practices that can be used at the point of production; the approach should be expanded to the balance of the farm-to-table continuum.

4. Priority International Activities

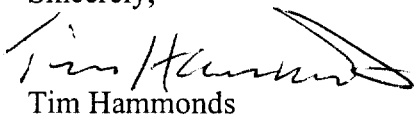
a. Safety of Imported Produce

In keeping with the Government Accounting Office's recommendations, FDA should develop a comprehensive surveillance system for monitoring imported produce at the borders. *See, e.g.*, "Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness" (GAO/RCED-92-224, August 1998). However, an effective program cannot simply begin and end at the U.S. borders; FDA must develop and implement a program to evaluate foreign food regulatory systems and to inspect processing plants and production facilities in other countries. That is, the Agency should not neglect the "farm" end of the farm-to-table continuum for imported produce.

* * *

We trust that you will agree that CFSAN should attend to the areas identified above in order to ensure the safety of the food supply. We hope that you will incorporate these issues into the coming year's workplan. If you have any questions regarding our recommendations, or if we may be of assistance in any way, please do not hesitate to call on us.

Sincerely,



Tim Hammonds
President and CEO